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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,919	09/08/2000	Mark D. Erion	030727.0035.UTL	2510

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EXAMINER

WILSON, JAMES O

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/16/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/657,919

Applicant(s)

ERION ET AL.

Examiner

James O. Wilson

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-158 is/are pending in the application.
- 4a) Of the above claim(s) 50-64, 89-103 and 119-154 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49, 65-87, 104-118 and 155-158 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____. |

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Claims 50-64, 89-103 and 119-154 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

In response to applicant's request for clarity, the two Groups from which applicant were intended to elect are indeed Group I: claims 1-133 and Group II: claims 134-157. The typographical error was properly identified and the relationship between Group I and claims 1-133 is correct as asserted by applicant's representative. In response to applicant's assertion that the inventions of Group I and II are not related as combination subcombination, the examiner notes that the recitation of a potential polycyclic phosphorous based prodrug moiety is broadly recited in Group I as such relates to formula I, but the omission of details of the subcombination claimed in Group II designated formula VII, specifically the relationship between variables W, W', V and Z essential to the structural core of formula I but not essential to the structural core of formula VII is sufficient evidence that the combination as set forth in Group I does not require the particulars of the specific subcombination set forth in Group II. Further, the examiner appreciates applicant's representative's opinion that the different inventions would not impose an undue burden is not true, in view of the fact that the structural core of formula I alone is cumbersome and will be difficult, hence the species requirement advanced to further limit the scope of independent and distinct inventions set forth in these claims.

In response to which restricted and separated species would "make more sense", the examiner offers that MH represents that which is directly attached to the phosphorous atom which is part of the core of the monocyclic structure with the requisite variables W, W', V and Z of formula I in Group I. Applicant enjoys the opportunity to select from those species advanced by the examiner or to offer an alternative grouping and an election correlative to same. No alternative election of species for the examiner to consider has been advanced, only an alternative suggestion of a different species grouping is set forth. Had applicant's representative offered a bona fide alternative and set forth the various claims that read on same, the examiner would have been able to weigh the suggestions and options. Since no viable alternative election of species has been set forth for the examiner to consider, the restriction and species requirements are FINAL.

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An action on the merits of claims 1-49, 65-88, 104-118 and 155-158 is contained herein below.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-49, 65-88, 104-118 and 155-158 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 95-97, 99-172 and 174 of U.S. Patent No. 6,312,662. Although the conflicting claims are not identical, they are not patentably distinct from each other because the core structure of the cyclic phosphate prodrug overlaps substantially, specifically when the variable Y is oxygen. Additionally, the identity of variables W, W', V and Z are all substantially overlapping. The examiner notes the major difference between the instant composition claims and the patented claims is in the scope of the heteroatoms attached to the phosphorus in the ring structure. In the instant invention the heteroatoms are selected from oxygen or amine linkages, however the patent limits the

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heteroatoms attached to the phosphorus atom to oxygen. The use of this class of compounds to affect a liver related condition is also seen to be obvious in view of claim 174 of the Erion et al. patent. It would be obvious to the skilled artisan that these compositions of matter and the method for administering same to affect a liver related condition are indeed prima facie obvious and to neglect to advance an obviousness double patenting rejection is to encourage the unjustified or improper timewise extension of the "right to exclude" granted by a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 1-49, 65-88, 104-118 and 155-158 are rejected under 35 U.S.C. 103(a)/102(e) as being obvious over the Erion et al. patent 6,312,662.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2). Although the conflicting claims are not identical, they are not patentably distinct from each other because the core structure of the cyclic phosphate prodrug overlaps substantially, specifically when the variable Y in the instant application is oxygen. Additionally, the identity of variables W, W', V and Z are all substantially overlapping. The examiner notes the major difference between the instant composition claims and the patented claims is in the

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scope of the heteroatoms attached to the phosphorus in the ring structure. In the instant invention the heteroatoms are selected from oxygen or amine linkages, however the patent limits the heteroatoms attached to the phosphorus atom to oxygen. The use of this class of compounds to affect a liver related condition is also seen to be obvious in view of claim 174 of the Erion et al. patent. It would be obvious to the skilled artisan that these compositions of matter due to the fact that each variable of the compositions instantly claimed overlap with those of the patent and the method for administering same to affect a liver related condition is indeed prima facie obvious.

Claims 1-49, 65-88, 104-118 and 155-158 are rejected under 35 U.S.C. 103(a) as being obvious over the Erion et al. patent 6,312,662 .

Claims 1-49, 65-88, 104-118, and 155-157 are drawn to a phosphate-containing compound wherein the active agent represented by the variable M is etoposide. Claim 158 is drawn to a method for treating diseases of the liver using a compound of claim 1. The examiner notes this claim is also limited to the elected species, which is etoposide.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Erion patent is seen to disclose compounds wherein a phosphate-containing compound wherein the active agent is intended to affect hyperlipidemic conditions, see claims 95 and 96. In column 32, the compound etoposide is specifically set forth as compounds suitable

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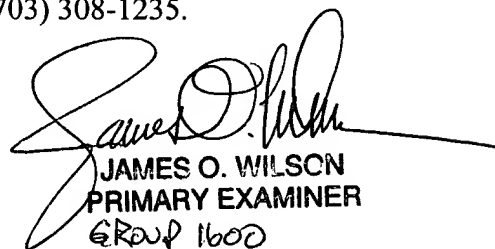
for conversion to compounds of formula I. The structure of formula I in claim 95 is seen to overlap substantially with the instantly claimed invention. Compounds in which two single bonds of oxygen attached directly to the phosphorus atom form the ring structure of the instant invention must be noted. In column 21, lines 61 through column 22, line 17, the prior art clearly sets forth the use of compounds sharing the same chemical core as that which applicant claims, for treating liver diseases and associated conditions.

It would have been obvious to one having ordinary skill in this art at the time the invention was made to obtain a cyclic phosphorus containing compound wherein all atoms attached directly to said phosphorus to form a ring are oxygen atoms and the biologically active agent is the saccharide derivative etoposide, because the Erion et al. patent discloses same as indicated supra. It requires little to find motivation to formulate compositions as applicant claims because the structural core of the prior art compounds represents a species of the broad genus applicant claims in the instant application. The method for treating liver disease or an associated condition is also seen to be disclosed in the prior art patent as set forth supra and the invention as claimed is indeed prima facie obvious in view of the Erion et al. patent .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James O. Wilson, Primary Examiner in Art Unit 1623 whose telephone number is (703) 308-4624. The examiner can normally be reached on Monday-Friday from 10:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600